Docket No.: 28594/41532
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Williams *et al.*

Application No.: 11/143,043

Group Art Unit: 1623

Confirmation # 8801

Filed: June 2, 2005

Examiner: Elli Peselev

For: GLYCOALKALOID COMPOSITIONS AND VARIOUS USES THEREOF

DECLARATION UNDER 37 C.F.R. § 1.132 OF DR. ELIZABETH WILLIAMS

Commissioner for Patents
P.O. Box 1450,
Alexandria, Virginia 22313-1450

Dear Sir:

I, Dr. Elizabeth Williams, do hereby declare and state as follows:

1. I am an inventor on the above-identified U.S. patent application (hereinafter, the "patent application"). I am a scientist, previously working at the Centre for Applied Cancer Studies in University of Western Australia. I am now working as a technical proofreader/editor for SRK Consulting Pty Ltd. I have a Ph.D. in Agricultural Science. A copy of my curriculum vitae is attached as Exhibit A.

2. I am familiar with the contents of patent application and with the official action from the United States Patent and Trademark Office (hereinafter, the "Patent Office") dated December 19, 2006, a copy of which is attached hereto as Exhibit B. A copy of the claims that I understand are pending in the reference application are attached hereto as Exhibit C.

3. In reviewing the Office action, I understand that by reciting the term "consisting essentially of" and by reciting the term "and is substantially free of mono- and diglycerides and free rhamnose" each of the claims that are attached in Exhibit C exclude mono-

and diglycerides and free rhamnose and also exclude any other materials that will affect the activity or characteristics of the composition being claimed.

4. However, I note that having stated the above, at page 3 of the Office action the Examiner has indicated that the above argument is "not persuasive" and that "[t]he has not pointed how the amount of the di- and mono-glycosides in the composition disclosed by Cham differs from the amount of said glycosides in the claimed compositions." I am providing the following remarks and description of data in order to provide evidence that glycoalkaloid compositions that contain di- and mono-glycosides and rhamnose are not as effective as the compositions that are substantially free of such components.

5. I am familiar with WO 91/10743, WO 00/6153 and AU-B-57853/80 (referred to herein as "the Cham documents"). It is my belief that the Cham documents relate to a composition known as BEC, which is a composition that contains solasonine, solamargine and di- and mono-glycosides and free sugar (rhamnose). I have performed experiments using BEC, and I describe these experiments below. I understand from discussions with Dr Carol Worth, Senior Scientist / Quality Manager at Solbec Pharmaceuticals Ltd (referred to herein as "Solbec"), that the BEC with which I was supplied and used for my studies was in turn supplied to Solbec by Dr Cham.

6. I am making this declaration in order to provide facts relating to properties of the compositions claimed in the subject application. In particular, I have performed cytotoxicity studies of BEC, solamargine and solasonine and have evidence that establishes that solamargine is considerably more potent than solasonine at killing cells; that there is a synergistic effect between solamargine and solasonine at the level of intracellular effect, and that BEC is not as effective as a 1:1 mixture of solasonine and solamargine alone.

7. BEC is the composition of the Cham documents. BEC is a crude preparation of glycoalkaloids that includes a substantial amount of di- and mono-glycosides and free rhamnose and other plant products. The crude BEC preparation of the Cham documents had a brown colour. It is my understanding, again from discussions with Dr Carol Worth, that this brown coloration of BEC is partly due to the Mailliard reaction and partly due to the quantity of co-extracted plant material, including phenolics which readily brown in air.

8. I performed original assays of BEC cytotoxicity in order to compare the effects a crude preparation on a range of cell lines derived from a variety of different cancerous tumours and from primary non-cancerous tissues.

9. For any given concentration of BEC, the number of glycoalkaloid molecules available to be taken up by each cell, and to then disrupt cellular processes, is determined directly by the number of cells present. The data for all cell lines was analysed by plotting the measured LD_{50}s as dose of BEC per cell against the number of cells in the population used for each determination. This yielded a bimodal distribution of points. At densities between 500 and 1500 cells per well the points for all cell lines, cancerous and non-cancerous, fell on a near vertical line. At densities between 4000 and 10000 cells per well the points fell on one of two horizontal lines. Points for all cancer cell lines except those derived from breast tumours fell on the lower line, reflecting an approximately three-fold higher sensitivity to BEC than non-cancerous and breast cancer cell lines, the points for which fell on a line three times higher on the Dose per Cell at LD_{50} axis.

10. A BEC preparation was compared with a 1:1 mixture of purified solamargine and solasonine, together with purified preparations of solamargine and solasonine under conditions in which receptor affinity is the predominant determinant of LD_{50} the following values were observed for cell line 786-O:

LD_{50}, µg/mL total glycoalkaloid			
1. BEC	**2. Solamargine**	**3. Solasonine**	**4. Solamargine + Solasonine (1:1 mixture)**
4.4	4.53	18.22	1.47

11. From the above data, it is my conclusion that:

a. solamargine has a higher affinity for the cell surface receptor that mediates its uptake by cells than solasonine has with the cell surface receptor mediating its entry into cells (compare column 2 with column 3);

b. solasonine and solamargine act synergistically with each other at the point of uptake into the cell, possibly through a co-operative effect between different receptors or through concurrent stimulation of the same receptor (compare column 2 and 3 with the data in column 4); and

c. BEC composition is not as effective as the isolated 1:1 solamargine:solasonine mixture (compare column 1 with column 4).

12. In addition to the data described in paragraph 10 above, experiments were performed in which a BEC preparation was compared with a 1:1 mixture of purified solamargine and solasonine, together with purified preparations of solamargine and solasonine under conditions in which the dose per cell was limiting for cytotoxic effect. This was examined for six different cell lines, including 786-O and showed the following data:

Dose per cell at LD_{50}, pg/cell of total alkaloid						
1. Cell line	**2. BEC**	**3. Solamargine**	**4. Solasonine**	**5. (1:1 mixture of the two glycoalkaloids)**	**6. Solamargine in 1:1 mixture**	**7. Solamargine in BEC**
NO36	298.0	154.8	613.2	148.4	74.20	74.50
LNCaP	428.5	121.9	432.5	117.3	58.65	107.13
LS174T	465.2	162.8	>400	171.6	85.80	116.30
A2058	247.0	199.0	685.0	78	39.00	61.75
786-O	321.2	208.0	>400	134.4	67.20	80.30
NHDF-Ad	283.3	209.2	584.0	156.8	78.40	70.83

13. From the above data, it is again my conclusion that:

a. solamargine is considerably more potent than solasonine at killing cells, as can be seen by comparing column 3 with column 4;

b. there is a synergistic effect between solamargine and solasonine at the level of intracellular effect, as can be seen by comparing columns 3 and 4 with column 5; and

c. BEC composition is not as effective as the isolated 1:1 solamargine:solasonine mixture, as can be seen by comparing column 2 with column 5.

14. From the above-reported data, it is my belief that the BEC composition is not as effective at cell killing or being taken up by the cells as a composition that consists of a 1:1 ratio of solamargine:solasonine.

15. I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Date April 2, 2007

Dr. Elizabeth Williams

APPENDIX A: CURRICULUM VITAE OF DR ELIZABETH WILLIAMS

Elizabeth Anne Williams B Agr Sc PhD (Tas) LLB (UWA)

Telephone: (08) 9244 7731 Mobile: 0409 779 043
email: e.a.williams@bigpond.com

CURRICULUM VITAE

PERSONAL DETAILS:

Name Elizabeth Anne Williams (nee Stronach)

Address 5 Craig Street, Wembley Downs, WA 6019

Nationality Australian citizen

EDUCATION:

1975 Admitted to degree of B Agr Sc (University of Tasmania)

1989 Admitted to degree of Ph D (University of Tasmania)

1998 Awarded Advanced Certificate in Principles of Protein Structure (University of London)

2006 Admitted to degree of LLB, (University of Western Australia)

2006- Currently studying for Graduate Diploma in Legal Practice with The College of Law, Sydney, NSW.

SCHOLARSHIPS:

1969-70 Australian Government Secondary Scholarship

1971-74 Australian Government University Scholarship

1971-74 Australian Agricultural Council Scholarship

EMPLOYMENT:

1975-77, 1979-1982, and 1985-86	Research Assistant, Faculty of Agricultural Science, University of Tasmania
1987-1989	Research Assistant to Dr AB Roy, John Curtin School of Medical Research, Australian National University
1989-1991	Postdoctoral Research Fellow with Professor JF Morrison John Curtin School of Medical Research, Australian National University
1992	Independent Postdoctoral Research Fellow, John Curtin School of Medical Research, Australian National University; and Research Associate, Research School of Biological Science, Australian National University
1993-96	Research Fellow and Laboratory Head, Lions Cancer Institute of Western Australia
1996-2002	Research Fellow and Laboratory Head, Centre for Applied Cancer Studies, University of Western Australia
1998-1999	Deputy Director, Centre for Applied Cancer Studies, University of Western Australia
1999-2003	Director, Centre for Applied Cancer Studies, University of Western Australia
2007	Technical Proofreader/Editor, SRK Consulting Engineers and Scientists

PROFESSIONAL MEMBERSHIPS:

1989-2003	Australian Society for Biochemistry and Molecular Biology
1993-2003	Australian Society for Medical Research
2005-	Student member of LEADR, Association of Dispute Resolvers

PROFESSIONAL COMMITTEE MEMBERSHIPS:

1992 Australian National University Staff Association

1992-93 National Research Policy Committee of the National Tertiary Education Union

SOME PAST EXTRA-CURRICULAR INTERESTS:

1979-82 Home tutoring Vietnamese refugees in English language through the Migrant Education Centre

1984-85 Fundraising for Bandung International School, Indonesia

CURRENT EXTRA-CURRICULAR INTERESTS:

1993-2006 Race control as Starter at Nedlands Yacht Club

2005 Coach, Schools Conflict Resolution and Mediation Competition, initiative of the Western Australian Dispute Resolution Association

1996- Rotary

1975- Occasional bushwalking

2005 Role player for LEADR Mediator accreditations

ARTICLES PUBLISHED IN INTERNATIONAL REFEREED JOURNALS

1. Menary, R. C., Williams, E. A. & Doe, P. E. (1983) Enzymic degradation of α-acids in hops. *Journal of the Institute of Brewing* ***89****, 200-203.*
2. Menary, R. C., Nickerson, G. B. & Williams, E. A. (1986) Effect of myrtenol on the rate of oxidation of α- and β-acids in hops. *Acta Horticulturae* ***188****, 149-156.*
3. Williams, E. A. & Menary, R. C. (1988) Polyphenolic Inhibitors of α-acid oxidase activity. *Phytochemistry* ***27****, 35-39.*
4. Williams, E. A. (1989) Inhibition of α-acid oxidase by polyphenolic compounds - a kinetic model. *Phytochemistry* ***28****, 1327-1330.*
5. Roy, A. B. & Williams, E. A. (1989) The sulphatase from Helix pomatia. Purification and kinetic properties. *Comparative Biochemistry and Physiology* ***93B****, 229-237.*

6. Williams, E. A. & Morrison, J. F. (1991) Characterisation of tightly-bound substrates in pure preparations of dihydrofolate reductase: implications for studies on enzymes. *Biochimica et Biophysica Acta. **1078**, 47-55.*
7. Williams, E. A. & Morrison, J. F. (1992) Human dihydrofolate reductase: reduction of alternative substrates, pH effects and inhibition by deazafolates. *Biochemistry **31**, 6801-6811.*
8. Trapani, J. A., Jans, P., Smyth, M. J., Froelich, C. J., Williams, E. A., Sutton, V. R. and Jans, D. A. (1998) Perforin-dependent nuclear entry of granzyme B precedes apoptosis, and is not a consequence of nuclear membrane dysfunction. *Cell Death and Differentiation 5, 488-496.*
9. Williams E. A., Hepler, P. K., Carrello, A. C., and John, P. C. L. (1999) Nuclear accumulation kinetics of p9CksHs1 and p9CksHs2 in live plant cells correlate with immunochemical characteristics. *Protoplasma 209, 98-105.*
10. Kelly J.A., Williams, E. A. and Wilce M. J. C (2005) Preliminary crystallographic analysis of the Cks protein $p13^{suc1P90AP92A}$ from *Schizosacharromyces pombe. European Biophysics Journal **34**, 430-433.*

INVITED LECTURES/SEMINARS

1. Australian Society for Biochemistry and Molecular Biology Mundaring Weir Conference 1993
2. University of Western Australia Biochemistry Department Seminar Series, 1993
3. John Curtin School of Medical Research, Australian National University, 1994
4. Department of Biochemistry, University of Cambridge, Cambridge, U. K., 1994
5. Cell Cycle Control Group, Imperial Cancer Research Fund, London, U. K., 1994
6. TVW Channel 7 Child Health Research Institute Seminar Series, 1995
7. Molecular Genetics and Cell Biology Discussion Group, Royal Perth Hospital, September 1996
8. Cell Cycle Satellite Meeting, Adelaide,1998
9. Cancer Council Cancer Conference, 2001
10. University of Western Australia Biochemistry Department Seminar Series, 2001

COMPETITIVE RESEARCH GRANTS AWARDED

1993	Royal Perth Hospital Medical Research Foundation
1994	Clive and Vera Ramaciotti Foundations
1995	Cancer Foundation of Western Australia
1995	Institute of Advanced Studies - Australian Universities Collaborative Research Scheme
1996	Lions International Foundation - for establishment of

	Molecular Modeling Computer Facility
1998	Royal Perth Hospital Medical Research Foundation
2001	Cancer Foundation of Western Australia

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/143,043	06/02/2005	Stephen John Carter	28594/41532	8801

7590 12/19/2006

Nabeela R. McMillian
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drvice, Suite 6300
Sears Tower
Chicago, IL 60606-6357

RECEIVED
DEC 27 2006
MARSHALL GERSTEIN

EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Docketed: 3-19-07

Office Action Summary	Application No.	Applicant(s)	
	11/143,043	CARTER ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 54-94 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cham (WO 00/61153).

Cham discloses the composition comprising glycoalkaloid composition , wherein essentially all free sugars (page 9, lines 33-38) and aglycones (page 10, lines 24-31) are removed. The claimed compositions are anticipated by Cham. In addition, if there are any differences between the claimed compositions and the prior art's compositions,

the differences would appear to be minor in nature and the claimed compositions, which fall within the scope of the prior art's compositions, would have been prima facie obvious from the said reference's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Applicant's arguments filed November 21, 2006 have been fully considered but they are not persuasive.

The terminology "consisting essentially of" (claim 54) limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s): if the claimed invention". "If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention." (MPEP 2111.03). In the present case Cham discloses removal of any sugars (page 9, lines 33-38) and removal of aglycones (page 10, lines 24-31) from a glycoalkaloid composition. Applicant contends that the Cham reference disclose a composition comprising solasonine (as 33% of the composition) and "solamargine (as 33% of the composition), and a third portion made up of di- and mono-glycosides and free sugar. This argument has not been found persuasive. Applicant has not pointed how the amount of di- and mono-glycosides in the composition disclosed by Cham differs from the amount of said glycosides in the claimed compositions. In the case that there are differences in the amounts, applicant has not provided any evidence that the larger amount of di and mono-glycosides would materially change the characteristics of

the applicant's composition. Further, Cham discloses that the composition "may be formulated from a synthetic glycoalkaloid or a mixture of glycoalkaloids" (page 5, lines 33-38). From the teaching by Cham, a person having ordinary skill in the art at the time the claimed invention was made would have envisaged a synthetic composition of a mixture of glycoalkaloids in the absence of di- and mono-glycosides.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200

APPENDIX B: OFFICIAL ACTION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE DATED DECEMBER 19, 2006

APPENDIX C: CLAIMS OF U.S. APPLICATION 11/143,043

54. [New] A composition consisting essentially of two glycoalkaloids selected from the group of glycoalkaloids consisting of: solamargine, solasonine, solanine, tomatine, solanocapsine and 26-aminofurostane and wherein the two glycoalkaloids are present in the composition at a ratio of between: 1:4 and 1:1.

55. [New] A composition according to claim 54 wherein the glycoalkaloids are solamargine and solasonine.

56. [New] A composition consisting essentially of about a 1:1 ratio of solamargine and solasonine.

57. [New] A composition according to claim 54 or 56 wherein the glycoalkaloids constitute 70%-90% of the composition.

58. [New] A composition according to claim 54 or 56 wherein the glycoalkaloids constitute 91-95% of the composition.

59. [New] A composition according to claim 54 or 56 wherein the glycoalkaloids constitute 96-100% of the composition.

60. [New] A pharmaceutical composition comprising an active ingredient composition consisting essentially of two glycoalkaloids selected from the group of glycoalkaloids consisting of: solamargine, solasonine, solanine, tomatine, solanocapsine and 26-aminofurostane and wherein the two glycoalkaloids are present in the composition at a ratio of between: 1:4 and 1:1 and a pharmaceutically acceptable carrier.

61. [New] A pharmaceutical composition according to claim 60 wherein the glycoalkaloids are solamargine and solasonine.

62. [New] A pharmaceutical composition comprising an active ingredient composition consisting essentially of about a 1:1 ratio of the glycoalkaloids solamargine and solasonine and a pharmaceutically acceptable carrier.

63. [New] The pharmaceutical composition of according to claim 60, 61, or 62 wherein the active ingredient forms between 0.1% to 10% of the pharmaceutical composition.

64. [New] A pharmaceutical composition according to claim 60, 61, or 62, wherein the glycoalkaloids constitute 70%-90% of the active ingredient in the pharmaceutical composition.

65. [New] A pharmaceutical composition according to claim 60, 61, or 62, wherein the glycoalkaloids constitute 91-95% of the active ingredient in the pharmaceutical composition.

66. [New] A pharmaceutical composition according to claim 60, 61, or 62, wherein the glycoalkaloids constitute 96-100% of the active ingredient in the pharmaceutical composition.

67. [New] A pharmaceutical composition according to claim 60, 61, or 62, wherein said composition is a topical delivery composition.

68. [New] A pharmaceutical composition according to claim 60, 61, or 62 wherein said composition is an oral delivery composition.

69. [New] A pharmaceutical composition according to claim 60, 61, or 62 wherein said composition is a parenteral delivery composition.

70. [New] A pharmaceutical composition of claim 63 wherein said composition is a topical delivery composition.

71. [New] A pharmaceutical composition of claim 63 wherein said composition is a oral delivery composition.

72. [New] A pharmaceutical composition of claim 63 wherein said composition is a parenteral delivery composition.

73. [New] A pharmaceutical composition of claim 64 wherein said composition is a topical delivery composition.

74. [New] A pharmaceutical composition of claim 64 wherein said composition is a oral delivery composition.

75. [New] A pharmaceutical composition of claim 64 wherein said composition is a parenteral delivery composition.

76. [New] A pharmaceutical composition of claim 65 wherein said composition is a topical delivery composition.

77. [New] A pharmaceutical composition of claim 65 wherein said composition is a oral delivery composition.

78. [New] A pharmaceutical composition of claim 65 wherein said composition is a parenteral delivery composition.

79. [New] A pharmaceutical composition of claim 66 wherein said composition is a topical delivery composition.

80. [New] A pharmaceutical composition of claim 66 wherein said composition is a oral delivery composition.

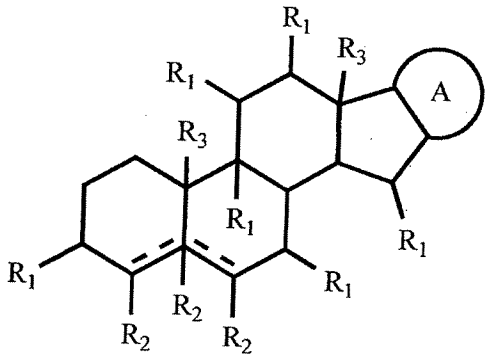
81. [New] A pharmaceutical composition of claim 66 wherein said composition is a parenteral delivery composition.

82. [New] A pharmaceutical composition according to claim 63, wherein the glycoalkaloids constitute 70%-90% of the active ingredient in the pharmaceutical composition.

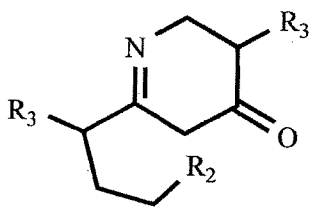
83. [New] A pharmaceutical composition according to claim 63, wherein the glycoalkaloids constitute 91-95% of the active ingredient in the pharmaceutical composition.

84. [New] A pharmaceutical composition according to claim 63, wherein the glycoalkaloids constitute 96-100% of the active ingredient in the pharmaceutical composition.

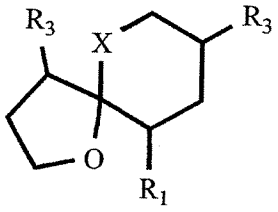
85. [New] A composition consisting essentially of two glycoalkaloids present in the composition at a ratio of between: 1:4 and 1:1 wherein the composition is essentially free of mono- or diglycosides, free sugars and aglycones, said glycoalkaloids having a formula of:



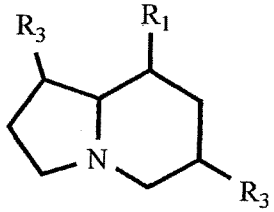
wherein: either one or both of the dotted lines represents a double bond, and the other a single bond, or both represent single bonds; A: represents a radical selected from the following radicals of general formulae (II) to (V):



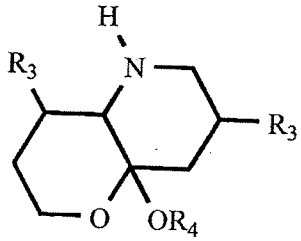
(II)



(III)



(IV)



(V)

each of R^1 is a radical separately selected from the group consisting of hydrogen, amino, oxo and OR^4;

each of R^2 is a radical separately selected from the group consisting of hydrogen, amino and OR^4;

each of R^3 is a radical separately selected from the group consisting of hydrogen, a carbohydrate and a carbohydrate derivative selected from the group consisting of a glyceric aldehyde, glycerose, erythrose, threose, ribose, arabinose, xylose, lyxose, altrose, allose, gulose, mannose, glucose, idose, galactose, talose, rhamnose, dihydroxyactone, erythrulose, ribulose, xylulose, psicose, fructose, sorbose, tagatose, and other hexoses, heptoses, octoses, nanoses, decoses, deoxysugars with branched chains, sugar alcohols, sugar acids, benzimidazoles, the enol salts of the carbohydrates, saccharinic acids, sugar phosphates;

"X" is a radical selected from the group consisting of $-CH_2-$, -O- and $-NH_2-$; and

wherein the compound includes at least one R^4 group that is a carbohydrate or a carbohydrate derivative selected from the group consisting of glyceric aldehyde, glycerose,

erythrose, threose, ribose, arabinose, xylose, lyxose, altrose, allose, gulose, mannose, glucose, idose, galactose, talose, rhamnose, dihydroxyactone, erythrulose, ribulose, xylulose, psicose, fructose, sorbose, tagatose, and other hexoses, heptoses, octoses, nanoses, decoses, deoxysugars with branched chain, sugar alcohols, sugar acids, benzimidazoles, the enol salts of the carbohydrates, saccharinic acids, sugar phosphates.

86. [New] A composition according to claim 85 wherein the glycoalkaloids constitute 70%-90% of the composition.

87. [New] A composition according to claim 85 wherein the glycoalkaloids constitute 91-95% of the composition.

88. [New] A composition according to claim 85 wherein the glycoalkaloids constitute 96-100% of the composition.

89. [New] A pharmaceutical composition in which the active ingredient consists essentially of the composition of claim 85, 86, 87 or 88 and is substantially free of mono- and diglycerides and free rhamnose.

90. [New] The pharmaceutical composition of 89 wherein said composition is a topical delivery composition.

91. [New] The pharmaceutical composition of 89 said composition is an oral delivery composition.

92. [New] The pharmaceutical composition of 89 said composition is an parenteral delivery composition.

93. [New] The pharmaceutical composition of 89 the active ingredient forms between 0.1% to 10% of the pharmaceutical composition.